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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/588,637	01/19/1996	ALAN G. BARBOUR	454312-2420	6046

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EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/588,637

Applicant(s)

BARBOUR ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-10, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicants' Reply to Supplemental Examiner's Answer, received 26 July 2004, is acknowledged. Applicants request reconsideration and withdrawn of the rejection of claims 1-4, 6-10, 12, and 13 and a Notice of Allowance.
2. Claims 1-4, 6-10, 12 and 13 are pending and under consideration.

Rejection Maintained

3. The rejection of claims 1-4, 6-10, 12, and 13 under the judicially created doctrine of obviousness-type double patenting as being patentable over claim 2 of U.S. Pat. No. 5,688,512 in view of Cohen is maintained.

Applicants' argue that the Supplemental Examiner's Answer is merely a rehash of the Examiner's Answer and fails to comply with the directions in the Remand "to prepare a substantive response to each point contained in the Reply Brief, taking into account the exhibits".

The Supplemental Examiner's Answer is silent as to the Exhibits to the Reply Brief.

Exhibit A = (unpublished) Ex parte Gambogi. Applicants Reply Brief mentions this reference to support their argument that the examiner has not referred to specific portions of Cohen.

Applicants are directed to the first Office Action, mailed 22 May 2000, which specifically cites Table 43-3, see discussion of Cohen below.

Exhibit B = cited Cohen reference. Applicants merely state that this Exhibit B, was attached in case Applicants and Examiner are working from different documents with respect to

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that which has been cited as Cohen. This exhibit was provided by Applicants "for the convenience of the Board".

The reference is specifically discussed in all preceding Office Actions, as well as the Supplemental Examiner's Answer.

Exhibit C = FDA panel backs Lyme disease vaccine. Applicants state that Ex. C. is provided for the convenience of the Board to take notice of a known fact that is also stated in the present application (see footnote 4), and in their Reply Brief that, based upon this cited reference, judicial notice be taken of the fact that commercially available Lyme Disease vaccines are and were administered by injection.

While the examiner did not specifically note Ex. C, the entire discussion of routes of administration of vaccines was based upon historical Lyme disease vaccination, and specifically upon col. 18, lines 30-38 of U.S. Pat. No. 5,688,512, which directs one of ordinary skill in the art that any immunization route may be contemplated or shown to produce an appropriate immune response can be employed in accordance with the principle of the present invention.

The Supplemental Examiner's Answer does not address many portions of the Reply Brief, pages 3-9 and 12-13.

While the examiner disagrees with Applicants' view that the discussion of the applicability of the references does not address many portions of the Reply Brief, the examiner requests which portions Applicants' deem "many portions".

Pages 3-9 of Applicants' Reply Brief discuss: 1) definition of the claim subject, mucosal/oral administration of various forms of OspA, and adjuvants, 2) discussion that Applicants' did not see in Cohen "various routes of administration with mucosal administration

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merely one route of several", 3) how the examiner failed to show motivation for modification of U.S. Pat. No. 5,688,512, and 4) OspA as a protein.

The examiner discussed in both the Examiner's Answer and the Supplemental Examiner's Answer, administration routes, forms of OspA, acceptable carriers or vehicles, and motivations for modifying Pat. No. 5,688,512.

The Supplemental Examiner's Answer fails to cite any portion of Cohen.

The entire reference is to be taken for the discussion of the rejection, even though there was a specific cited portion of Cohen was given to Applicants in the first Office Action, mailed 22May2000, which states on page 4 of the Office Action, "Cohen-----teaches various routes of administering vaccines such as subcutaneous, intradermal, intramuscular and oral. (see especially Table 43-3)." Subsequent explanations by the examiner stated that Cohen, as a whole, cited Cohen reference is directed to the field of Immunization, particularly the modes of immunization, types of immunization, and the benefits and hazards of immunization. Thus, consideration of the entire reference teachings indicate that oral/mucosal administration of the instantly claimed composition was only an obvious variant of the many routs of administration available.

The Supplemental Examiner's Answer fails to substantively respond to each of Applicants' arguments for the separate patentability of the claims.

The examiner did address the arguments concerning Applicants' recitation concerning the limitations of the various claims, e.g., adjuvants (claim 6), oral administration (claims 3, 4,

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6, 9, 12, and 13), mucosal administration of lipidated rOspA (claims 2 and 8) and oral administration of lipidated rOspA (claim 9). While the specific claims were not elucidated, the limitations contained within each claim were discussed in light of the cited references.

Conclusion

4. No claims are allowed.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.


If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 18, 2005


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER